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A Patent Pool-Party: Changing the Current Use of Patent Pools for Treatment Innovation in Public Health Emergencies

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NOTE

A PATENT POOL-PARTY: CHANGING THE CURRENT USE OF PATENT POOLS FOR TREATMENT INNOVATION IN PUBLIC HEALTH EMERGENCIES

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I. INTRODUCTION

Patent pools have been utilized since the 1800s to further innovation.[1] The efficacy of patent pools, however, has been debated because of their potential to hinder the market, subsequently harming innovation and growth.[2] There is an ongoing need for lifesaving medications and treatments for a myriad of diseases and emergency medical situations. With this, the question arises of who should be able to own such pertinent information, or if the better solution is to require such information to be collaborative. Further, understanding the best ways to share such inventive and vital lifesaving treatments and pharmaceuticals can positively impact national and worldwide public health. Is more legal and governmental intervention needed to ensure critical information is shared to advance public health?

The history of patent pools, the relationship with antitrust law, and the importance of public health all shed light on the best ways to share important information while keeping the competitiveness of the market alive. This Note discusses the benefits and weaknesses of patent pools, and how they influence public health and lifesaving medication information sharing. It also discusses a possible route forward for greater sharing of public health intellectual property in public health emergencies: government-enforced mandatory patent pools.

II. BACKGROUND

A. WHAT ARE PATENT POOLS?

To begin, patent pools cannot be understood without a general knowledge of patents and their history. The first patent act was signed in 1790 by George Washington.[3] Patents create exclusive rights for inventions that find a "new way of doing something, or offer[] a new technical solution to a problem."[4] The rights created by patents include the right to prevent others from commercial use

[1] *Patent Essentials*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/basics/essentials#questions (last visited Jan. 1, 2024).

[2] *See Sheila F. Anthony, Antitrust and Intellectual Property Law: From Adversaries to Partners, FTC (May 5, 1999)*, https://www.ftc.gov/news-events/news/speeches/antitrust-intellectual-property-law-adversaries-partners#II.%20Evolution (sharing the history and interplay of patents and antitrust law).

[3] *See Patent Essentials*, *supra* note 1 (detailing the early history of U.S. patent law).

[4] *Patents*, WORLD INTELL. PROP. ORG., https://www.wipo.int/patents/en/ (last visited Jan. 1, 2024).

and exploitation of an invention.[5] When a patent is filed, its lifespan typically lasts around twenty years after the filing date of the patent application.[6]

There are three types of patents: utility patents, design patents, and plant patents.[7] The United States Patent and Trademark Office ("USPTO") grants patents, administers patent law, records patent assignments, educates the public about patent law, and more.[8] Yet the USPTO does not have the authority to enforce patents.[9] Rather, "[p]atent rights are usually enforced in a court on the initiative of the right owner. In most systems a court of law has the authority to stop patent infringement. However[,] the main responsibility for monitoring, identifying, and taking action against infringers of a patent lies with the patent owner."[10]

Patents benefit society by encouraging innovation that aids human life and societal wellbeing.[11] When multiple parties are working in the same inventive space for commercial purposes, patent pools further innovation while also adhering to intellectual property laws and patent rights.[12] Patent pools are defined as "agreement[s] between two or more patent owners to license one or

[5] *See id.* ("[P]atent protection means that the invention cannot be commercially made, used, distributed, imported or sold by others without the patent owner's consent.").

[6] *Id.*; *see also Frequently Asked Questions: Patents*, WORLD INTELL. PROP. ORG., https://www.wipo.int/patents/en/faq_patents.html#:~:text=Once%20a%20patent%20expires%2C%20the,invention%20without%20infringing%20the%20patent (last visited Jan. 1, 2024) ("Once a patent expires, the protection ends, and an invention enters the public domain; that is, anyone can commercially exploit the invention without infringing the patent.").

[7] *Utility Patent vs. Design Patent: What Does Each Protect?*, COL. L. SCH. (Oct. 5, 2022), https://execedonline.law.columbia.edu/blog/starting-a-business/utility-patent-vs-design-patent/ ("A utility patent legally protects what a single invention does, how it is used, and how it works . . . . In other words, utility patents protect the detailed function of a product . . . . Design patents legally protect what an invention or creative work looks like, its shape and configuration, and any specific ornamentation or coloration . . . . Compared with utility patents, design patents protect the form of a product."); *General Information About 35 U.S.C. 161 Plant Patents*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/basics/apply/plant-patent (last visited Jan. 20, 2024) ("A plant patent is granted by the United States government to an inventor (or to the inventor's heirs or assigns) who has invented or discovered and asexually reproduced a distinct and new variety of plant, other than a tuber propagated plant or a plant found in an uncultivated state."); U.S. PAT. & TRADEMARK OFF.*, supra* note 3.

[8] *Id.*

[9] *Id.*

[10] *Frequently Asked Questions: Patents*, *supra* note 6.

[11] *Id.*

[12] *See* John DeQ. Briggs, *Intellectual Property and Antitrust: Two Scorpions in a Bottle*, 10 SEDONA CONF. J. 65, 82 (2009) ("Patent pools are formed when multiple patented technologies are needed to produce a standardized product. . . .").

more of their patents to one another or to third parties."[13] Patent pools are generally created to "supply [organizations] with the necessary technologies to develop compatible products and services" as well as to help develop new products and to reduce transaction costs.[14] Patents alone, as noted above, are created to prevent others from using one's creation and therefore they create a right to exclude.[15] Patent pools, on the other hand, are "legal mechanism[s]" created to share and waive this exclusive intellectual property right to allow multiple organizations to work together towards a common goal.[16]

Patent pools "can be either 'open' or 'closed' depending on the level of exclusivity the patent holder desires."[17] Patent pools are typically formed in an industry when there are multiple competing organizations that each hold vital pieces of technology to the innovation of a particular product.[18] "The patent pool establishes methods of patent valuation and for dividing royalty stream generated through licensing. Patent pools offer a mechanism for solving the problem, which arise when different inventors patent different components of an invention that uses both."[19]

When looking at "the nature of pooled technologies/patents, they can be categorized as (i) complementary or (ii) substitutes and, in a standard setting environment, as (iii) essential or (iv) non-essential. These categories are important for assessing the impact on competition . . . ."[20] Regarding standard setting patents, "[s]tandard essential patents, or SEPs, are patents that have been declared essential to a given technical standard."[21] When examining SEPs, the

[13] *Patent Pools and Antitrust – A Comparative Analysis*, WORLD INTELL. PROP. ORG. 3 (Mar. 2014), https://www.wipo.int/export/sites/www/competition-policy/en/docs/patent_pools_report.pdf.

[14] *Id.*; *see also* Michael Renaud et al., *The Patent Pool Explained: An Effective Mechanism, When the Burden is Shared*, IPWATCHDOG (Oct. 30, 2020), https://ipwatchdog.com/2020/10/30/the-patent-pool-explained-an-effective-mechanism-when-the-burden-is-shared/id=126859/ (noting that pools aid both innovators and implementers by stabilizing costs while improving efficiency).

[15] Joshua A. Newberg, *Antitrust, Patent Pools, and the Management of Uncertainty*, 3 ATL. L. J. 1, 2 (2000).

[16] *Id.*

[17] Chase A. Marshall, *A Comparative Analysis: Current Solutions to the Anticommons Threat*, 12 J. HIGH TECH. L. 487, 502 (2012); *see id.* at 509 ("For competing companies who each hold a vital patent for part of a technology, the closed patent pool best serves their interests because the companies are able to utilize each other's patents while still maintaining exclusive access to the patents. . . . One benefit of an open patent pool is that they can serve a larger group of users by broadening the access to technologies.").

[18] *Id.* at 509.

[19] Carol M. Nielsen & Michael R. Samardzija, *Compulsory Patent Licensing: Is It a Viable Solution in the United* States?, 13 MICH. TELECOMM. & TECH. L. REV. 509, 530 (2007).

[20] *Patent Pools and Antitrust – A Comparative Analysis*, *supra* note 13, at 4.

[21] *USPTO and WIPO Agree to Partner on Dispute Resolution Efforts Related to Standard Essential Patents*, U.S. PAT. & TRADEMARK OFF. (July 20, 2022), https://www.uspto.gov/about-us/news-updates/uspto-and-wipo-agree-partner-dispute-resolution-efforts-related-standard.

conversation is typically focused on "the terms of the licensing practices of technologies that are covered by a patent pool and are deemed standard-essential."[22]

Patent pools help with the creation of industry standards by creating a way for "standard essential patents" to be easily shared.[23] Companies prefer to have their patent seen as standard-essential because it allows for higher demand.[24] "By requiring F/RAND terms, a balance is achieved because patent owners benefit from the promotion of their technologies due to the classification as standard essential which potentially leads to higher licensing revenues, and licensees benefit from F/RAND terms."[25]

B. VOLUNTARY AND COMPULSORY LICENSING

Patent pools frequently use voluntary licensing.[26] Voluntary licensing is "the practice of extending a licensing agreement by the patent holder to a third-party generic participation for the expressed purpose of the third-party's use to create a generic version of the patented product."[27] With a voluntary license, there is typically a quality requirement in place and a definition of what market the license product can be sold in.[28]

On the other hand, compulsory licensing is a longstanding tool that has been utilized in intellectual property to get around the consent of patent owners.[29] In contrast to voluntary licensing, "[c]ompulsory licensing is when a government

[22] *Patent Pools and Antitrust – A Comparative Analysis*, *supra* note 13, at 8.

[23] *See* Russ Krajec, *How Patent Pools Work*, BLUEIRON (Jan. 26, 2022), https://blueironip.com/how-patent-pools-work/ (noting also that "[t]he key to a patent pool is that the patents are essential to meet the [industry] standard").

[24] *Patent Pools and Antitrust – A Comparative Analysis*, *supra* note 13, at 8.

[25] *See id.* (citation omitted) (defining F/RAND as "fair, reasonable and non-discriminatory).

[26] *See generally Our Strategy*, MEDS. PAT. POOL, https://medicinespatentpool.org/what-we-do/strategy (last visited Jan. 1, 2024) (stating how the Medicine's Patent Pool utilizes voluntary licensing).

[27] Daniel D. Kim, *Voluntary Licensing of Pharmaceuticals: The Strategy Against Compulsory Licensing*, 8 AM. U. 63, 80 (2016) (citation omitted).

[28] *Voluntary Licenses and Non-Assert Declarations*, INT'L FED'N PHARM. MFRS. & ASS'NS (July 28, 2010), https://www.ifpma.org/news/voluntary-licenses-and-non-assert-declarations/; *see also* Philip Stevens, *Why Voluntary Licensing is Best for Increasing Access to Medicines,* IPWATCHDOG (Jan. 10, 2023, 12:15 PM), https://ipwatchdog.com/2023/01/10/voluntary-licensing-best-increasing-access-medicines/id=155117/ (stating that the aid of treatment to low and middle income countries is thanks to voluntary licensing where "[i]nnovators license their IP and technology to global partners, who use their manufacturing muscle and local market presence to deliver reliable supplies of quality medicines and vaccines to patients globally").

[29] *Compulsory Licensing of Pharmaceuticals and TRIPS*, WTO, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Jan. 1, 2024, 2:04 PM).

allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself."[30] Compulsory licensing was codified by the World Trade Organization ("WTO") in the 1994 Trade-Related Aspects of Intellectual Property Rights ("TRIPS") agreement.[31] Compulsory licensing has been utilized by the WTO in the TRIPS agreement since January 1995.[32] When compulsory licenses are used, the patent owner holds their patent rights and is paid when copies of the product are produced under the compulsory license.[33] The purpose of compulsory licensing is to help provide essential and lifesaving medications to low-income countries and to aid in the distribution of these medications during public health emergencies.[34] The WTO stated that it "recommended that certain requirements for granting a compulsory license be waived 'in the case of a national emergency or other circumstances of extreme urgency.'"[35] With the longstanding creation of compulsory licenses and the WTO's promotion of public health over intellectual property rights, sharing information for public health is nothing new.

There have been noted benefits of compulsory licensing. These include that they "increase competition, . . . supply the market, and possibly reduce prices."[36] Some drawbacks to compulsory licensing include reduction of innovation, deterrence of research because of lack of incentive, their confrontational nature, creation of risk, and their unsustainability.[37] Overall, because voluntary licensing

[30] *Id.*; *see also* Peter B. Bach et al., *Compulsory Licensing of Pharmaceuticals in High-Income Countries: A Comparative Analysis*, NAT'L LIBR. MED. (Mar. 7, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8932629/#:~:text=Compulsory%20licensing%20is%20a%20practice,before%20the%20original%20patent%20expires ("Compulsory licensing is a practice whereby national authorities can license a third party to produce a patented product, such as a pharmaceutical drug, effectively enabling the production of a generic before the original patent expires.").

[31] Bach et al., *supra* note 30.

[32] *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 29.

[33] *Id.*

[34] Bach et al., *supra* note 30.

[35] *Id.* (citations omitted); *see also* Shuwen Xu, *To Waive or Not to Waive: The Debate and Analysis of Trips Waiver*, 18 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 423, 428 (2023) ("Compulsory licensing is critical when a much-needed patented drug is not widely available or unaffordable to citizens in a country.").

[36] Alberto do Amaral Jr., *Compulsory Licensing and Access to Medicine in Developing Countries*, YALE L. SCH. (2005); *see also id.* ("It is considered, in certain cases, that access to the invention should have priority over the private interest of the patent-holder and his exclusive right to exploit it.").

[37] Kirby W. Lee, *Permitted Use of Patented Inventions in the United States: Why Prescription Drugs Do Not Merit Compulsory Licensing*, 36 IND. L. REV. 175, 180 (2003); Philip Stevens, *Voluntary Licensing is Best for Increasing Access to* Medicines, IPWATCHDOG (Jan. 10, 2023), https://ipwatchdog.com/2023/01/10/voluntary-licensing-best-increasing-access-medicines/id=155117/#:~:text=will%20be%20key.-,Confrontational%20approaches%20such%20as%20compulsory%20licensing%20are%20time%20consuming%2C%20risky,should%20be%20the%20guiding%20principle.

agreements can be ended by mutual agreement, compulsory licensing within patent pooling creates a more effective mechanism to aid in pharmaceutical and treatment innovation when time is of the essence.[38]

C. PATENT POOL HISTORY AND INTERCONNECTION WITH ANTITRUST LAW

The first patent pool was created in 1856 to help further the innovation of the sewing machine.[39] Patent pools survived without any antitrust criticism until the creation of the Sherman Antitrust Act in 1890.[40] Litigation of patent pools began in 1895 and involved the National Harrow patent pool that delt with spring-tooth harrows, an agricultural tool used to prepare soil.[41] In *National Harrow Co. v. Quick*, the district court relayed its feelings of caution around promoting "combinations, trusts, or monopolies . . . . [Because] they have already grown to alarming proportions, and courts . . . ought to discountenance and repress them[,]" as the interplay of patent pools and antitrust law began to be seen as two sides of the same coin.[42]

The Supreme Court first dealt with patent pools in 1902 in *E. Bement & Sons v. National Harrow Co.*[43] There, the Supreme Court upheld the patent pool's legality even though there was a restraint on competition and noted that "rights under patent law trumped other concerns, including antitrust concerns under the Sherman Act of 1890."[44] Yet the Supreme Court later noted the importance of antitrust law in its relation to patent law in *Standard Sanitary Manufacturing Co. v. United States*.[45] The Court found that where antitrust law restrains patent law, this restraint can be found valid, creating the longstanding tug of war between the two areas of law.[46]

Today, patent pools' intersection with antitrust law creates complexities such as illegal and anticompetitive pools.[47] These laws can create issues and display

[38] Neil Davey, *Overcoming Patent Barriers to Increase Access to Medicines: A New Path Forward for Compulsory Licensing*, 35 HARV. J. L. & TECH. 689, 713 (2022).

[39] Gavin Clarkson & Joshua Newberg, *Blunt Machetes in the Patent Thicket: Modern Lesson from the History of Patent Pool Litigation in the United States Between 1900-1970*, 22 J. TECH. L. & POL'Y 1, 18 (2018).

[40] *Id.*

[41] *Id.*

[42] 67 F. 130, 132 (C.C.D. Ind. 1895), *aff'd,* 74 F. 236 (7th Cir. 1896).

[43] 186 U.S. 70 (1902).

[44] Clarkson & Newberg, *supra* note 39, at 20.

[45] 226 U.S. 20 (1912).

[46] Clarkson & Newberg, *supra* note 39, at 24.

[47] *See* Carl W. Schwarz et al., *The Intellectual Property/Antitrust Interface*, NO. 7 ANDREWS ANTITRUST LITIG. REP. 15 (2000) ("The application of antitrust laws to situations involving intellectual property 'present[s] a dizzying array of complexities that . . . [can] confuse even the ablest judge – let alone a jury' due to the conflicting purposes of these laws." (quoting David T. Pritikin & Bruce M. Zessar, *Antitrust Claims Based on Patent Enforcement: Walker Process, Handgards, and the Sham Litigation Doctrine*, PLI PATENTS, COPYRIGHTS, TRADEMARKS,

competing values but can also work together: "The aims and objectives of patent and antitrust laws may seem, at first glance, at odds. However, the two bodies of law are complementary, as both are aimed at encouraging innovation, industry and competition."[48]

The Department of Justice ("DOJ") and the Federal Trade Commission ("FTC") jointly issued the Antitrust Guidelines for Licensing and Intellectual Property ("IP Guidelines") in 1995.[49] These guidelines have three guiding principles: (1) intellectual property and other forms of property are treated the same by general antitrust principles; (2) it is not presumed "that intellectual property creates market power in the antitrust context[;]" and (3) intellectual property rights shall generally be perceived as "procompetitive" by agencies.[50]

These principles apply to patent pools, as the guidelines specifically regard patent pooling as "'procompetitive' because these arrangements can promote the dissemination of technology."[51] "Possible procompetitive effects result from: 1) clearing blocking positions; 2) avoiding costly infringement litigation; 3) integrating complementary technologies; and 4) reducing transaction costs."[52] Specifically, the IP Guidelines note that patent pools are procompetitive when they "[i]ntegrate[] complementary technologies," "[r]educe[] transaction costs," "[c]lear[] blocking positions," "[a]void[] costly infringement litigation[,] or" "[p]romote[] the dissemination of technology."[53] In regard to open or closed patents, the IP Guidelines state that "exclusion from pooling arrangements among parties that collectively possess market power may, under some circumstances, harm competition."[54] The IP Guidelines note that pooling arrangements among competing technologies likely will not have an anticompetitive effect unless "[e]xcluded firms cannot effectively compete in the relevant market for the good incorporating the licensed technologies," "[t]he pool participants collectively possess market power in the relevant market[,] and" "[t]he limitations on participation are not reasonably related to the efficient development and exploitation of the pooled technologies."[55]

& LITERARY PROPERTY COURSE HANDBOOK SERIES No. G4-3968, 449, 498–99 (1996) (alterations in original))).

[48] Anthony, *supra* note 2 (quoting Atari Games Corp. v. Nintendo of Am., Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990)); *see also id.* (noting that antitrust and patent laws were first thought of as at odds with one another, but as the law evolved there has been recognition of "a much closer and interconnected relationship between antitrust law and intellectual property rights").

[49] *Id.*

[50] *Id.*

[51] *Id.* (citation omitted).

[52] *Id.*

[53] *Patent Pools and Antitrust – A Comparative Analysis*, *supra* note 13, at 12.

[54] *Id.*

[55] *Id.* at 13.

The DOJ and FTC, when pools are thought to be anticompetitive, evaluate "whether the arrangement's limitations on participation are reasonably related to the efficient development and exploitation of the pooled technologies and will assess the net effect of those limitations in the relevant market."[56]

Patent pools tend to create problems regarding antitrust law "when the pools are composed of pure substitute patents covering technologies that compete with each other, rather than complementary patents covering separate aspects of a given technology that do not compete with each other."[57] When patents and antitrust law interact, "[p]atent holders violate the Sherman Act by pooling their patents and fixing prices for themselves and their licensees. Patent pooling also violates the Act where the combining patent owners effectively dominate the industry."[58] Patent pools can avoid antitrust issues when there is "an anticompetitive purpose or impact . . . which includes a uniform royalty rate on licensees under the pooled patents . . . ."[59]

The DOJ is the entity that reviews whether patent pools are creating antitrust violations.[60] The first business review letter involving antitrust issues and patent pools was issued on June 26, 1997.[61] The Antitrust Division of the DOJ considers the following factors to determine if a patent pool is anticompetitive: "(1) the adverse effects of the arrangement on downstream market competitors; (2) the potential that the arrangement will allow for collusion to occur on things outside of the pooled patent portfolio; and (3) the likelihood the arrangement will necessarily restrain competition in technology and innovation markets."[62]

The Antitrust Division also looks to see whether the patent pool requires "essential patent mechanisms."[63] The purpose of this is to "ensure that the portfolio patents do not involve competing technologies and that the portfolio licensed does not, by bundling in non-essential patents, foreclose competitive implementation of options."[64]

The FTC also ensures that patent pools follow antitrust laws to make sure that organizations within the pools are not fixing prices and monopolizing products.[65] Factors considered under Section One of the Sherman Act to decide whether patent pools unreasonably restrain competition include:

[56] *Id.*
[57] Briggs, *supra* note 12.
[58] 54 AM. JUR. 2d *Monopolies and Restraints of Trade* § 127 (citations omitted).
[59] *Id.*
[60] Schwarz, et al., *supra* note 47, at 16.
[61] *See* Richard J. Gilbert, *Antitrust for Patent Pools: A Century of Policy Evolution*, 2004 STAN. TECH. L. REV. 3, 4 (2004) (noting that DOJ business review letters provide guidance to patent pools to ensure their compliance with antitrust laws).
[62] Schwarz et al., *supra* note 47, at 27.
[63] *Id.*
[64] *Id.*
[65] *Id.*

> [T]he relationship among the patents in the pool[;] . . . . whether the relevant patents are available only through the pool license[;] . . . whether the pool limits those who may license from the pool, or whether it discriminates against certain licensees[;] . . . . the effect the patent pool will have on incentives to innovate and to invest in research and development[;] . . . . [and] whether the pool facilitates unlawful coordination among manufacturers of products implementing the pooled technology.[66]

All Sherman Act factors must be considered to determine whether overall competition has been reduced.[67]

When considering modern-day antitrust issues, the factors observe "[w]hether a pooling arrangement is likely to be procompetitive or anticompetitive [which] is substantially determined by the economic relationship of the pooled patents."[68] Overall, patent pools are procompetitive by "integrating complementary technologies, reducing transaction costs, clearing blocking positions and promoting the dissemination of technology."[69]

D. PATENT POOLS AND PHARMACEUTICALS

Patent pools have been widely used in areas "dominated by technology standards," but have less presence in areas such as medicine and pharmaceuticals.[70] There has been some use of patent pools within the pharmaceuticals sphere to increase access to medications, specifically in times of health crises.[71] The advantage of using patent pools within public health "is that bundling such knowledge together can lower transaction costs and more quickly increase access to medicines worldwide."[72]

Intellectual property laws, and specifically patents, have been viewed as obstacles to medication and treatment access.[73] When analyzing these obstacles

> the problem of patents foreclosing research on diseases disproportionately affecting developing countries is twofold:

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[66] *Instruction 3: Sherman Act Section 1--Rule of Reason*, ABA MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, ch. 4 § E (2016).

[67] *Id.*

[68] Newberg, *supra* note 15, at 3.

[69] Briggs, *supra* note 12, at 82; *see id.* (stating that patent pools "are unlikely to have anticompetitive effects unless (1) excluded firms cannot effectively compete in the relevant market for the good incorporating the licensed technologies and (2) the pool participants collectively possess market power").

[70] Clarkson & Newberg, *supra* note 39, at 111.

[71] Davey, *supra* note 38, at 708.

[72] *Id.*

[73] *Id.* at 713.

> (1) patents inhibit [research and development] because the market drives drug development and the limited exclusivity on the resulting drugs does not incentivize research for drugs with low profit margins; and (2) navigating the anticommons and patent thicket problems can be prohibitively costly and time-consuming.[74]

Although some forms of intellectual property can inhibit innovation of pharmaceuticals, it is possible that intellectual property can be used in a way that aids public health, if used appropriately.[75]

III. ANALYSIS

The recent COVID-19 pandemic illuminated and exacerbated the current issues involving how intellectual property law and regulation interacts with innovation within the public health sphere.[76] There have been examples seen throughout United States history that model good and bad interactions between IP law and public health. These past examples call into question the importance of IP laws in the wake of public health emergencies and whether public health should ever trump IP or antitrust concerns.

Even though "enforcement of intellectual property protection may be one approach to incentivize research and development, critics argue that this not only leads to high prices and rationing but also fails to incentivize products targeting populations that do not represent commercially attractive market[s] . . . ."[77] This Note argues that mandatory patent pools in times of public health emergencies, coupled with other intellectual property tools, can create a helpful solution to intellectual property blockages to public health innovation.

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[74] Ann Weilbaecher, *Diseases Endemic in Developing Countries: How to Incentivize Innovation*, 18 ANNALS HEALTH L. 281, 286 (2009).

[75] *See* James Love, *Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D*, 40 U.C. DAVIS L. REV. 679, 694 (2007) ("Increased use of patent pools and collective management of IP rights can foster access to patented medicines and improve the traditional patent system. This collective management will streamline patent procedures globally and lower costs.").

[76] *See* Brook K. Baker & Rachel D. Thrasher, *From Business as Usual to Health for the Future: Challenging the Intellectual Property Regime to Address Covid-19 and Future Pandemics*, 41 B.U. INT'L L. J. 1, 40 (2023) ("What is clear is that future pandemic responses should include major IP reform . . . .").

[77] *Intellectual Property and Access to Health Technologies*, UNAIDS, https://www.unaids.org/sites/default/files/media_asset/JC2820_en.pdf (last visited Jan. 1, 2024, 2:42 PM).

A. PAST EMERGENCY PUBLIC HEALTH IP RESPONSES

The COVID-19 pandemic brought to light the pitfalls of the current interplay of IP law and public health in emergency health situations. The pandemic created an opportunity for people and organizations to attempt to aid in treatment during a public health emergency. There have been past public health emergencies that prompted government response involving the intersection of IP and public health. Most recently, during the COVID-19 pandemic, lesser developed countries experienced a disproportionate harm to public health from the virus through "higher numbers of cases, higher numbers of deaths, and greater percentage of cases per 100,000 members of the population."[78] This experience prompted later government action.

One prominent IP response during the recent pandemic was the COVID-19 Technology Access Pool ("C-TAP") that was created to share treatments and health innovations regarding the COVID-19 pandemic.[79] Further, there was a waiver of patent and IP rights during the COVID-19 pandemic called the Trade-Related Aspects of Intellectual Property Rights ("TRIPS") waiver, that "suspend[ed] certain requirements regarding the use of COVID-19 vaccine patents, such as ingredients and manufacturing processes."[80]

This waiver allowed "states [to] authorize domestic manufacturers to produce COVID-19 vaccines without the permission of the patent rights holder and, crucially, to export those vaccines to other countries."[81] This waiver related to the TRIPS Agreement that, in 1994, was signed by WTO members to set a baseline of requirements to ensure certain intellectual property protections were internationally upheld.[82] In 2001, WTO members recognized the need "to increase access to affordable medicines in poor countries" and signed the Doha Declaration that "confirm[ed] members' right to use TRIPS flexibilities to advance health goals."[83] A waiver of IP rights is a step in the right direction and could work in tandem with a mandatory patent pool to provide the best intellectual property right sharing in a public health emergency, but a waiver on its own is not enough to pool appropriate knowledge.

The WTO, as noted above, has also worked with compulsory licensing to help provide access to medications during public health emergencies.[84] Although compulsory licensing is similarly a government-enforced system that aids in

[78] 7 JOHN G. MILLS III ET AL., *Waiver and Exceptions to the WTO Treaty and TRIPS Requirements*, PAT. L. FUNDAMENTALS § 21C:40 (2d ed.).

[79] Baker & Thrasher, *supra* note 76, at 19.

[80] Christopher Borges, *TRIPS Waivers and Pharmaceutical Innovation*, CTR. FOR STRATEGIC & INT'L STUD. (Mar. 15, 2023), https://www.csis.org/blogs/perspectives-innovation/trips-waivers-and-pharmaceutical-innovation.

[81] *Id.*; Mills, *supra* note 78.

[82] Xu, *supra* note 35, at 427.

[83] *Id.* at 428.

[84] *Id.*

trumping IP laws when public health is in crisis, a mandatory patent pool as a form of IP response could be more effective. First, compulsory licensing is less effective than patent pools because the compulsory process is slow due to negotiations required across multiple countries.[85]

During multiple public health emergencies, not just the COVID-19 pandemic, the WTO Council has allowed a temporary waiver of IP rights to allow countries with lower economic advantages to import cheaper drugs for ailments such as HIV, tuberculosis, and malaria.[86] In regard to treating HIV, intellectual property has played a large role in treatment and access to care. Prior to 1994, before TRIPS, countries created their own patent protections.[87] Then, after TRIPS in 1995, twenty-year patent protection for inventions was implemented.[88] After the Doha Declaration, WTO members affirmed that "TRIPS 'can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.'"[89]

When the Doha Declaration was implemented in 2001, however, HIV/AIDS was already a public health emergency, causing 9,000 deaths per day.[90] The constraints of intellectual property law had already failed those in need of treatment for HIV and AIDS at this point, greatly harming public health.

Past public health emergencies show just how much IP law can negatively influence public health.[91] The constraints of IP laws on public health treatment success in emergency situations "may be exacerbated if the technologies needed to address the pandemic are closely held by individual private enterprises with

[85] *See id.* at 428–29 ("The process of getting compulsory licensing is very complex and slow, as separate negotiations between countries and companies are required. Addressing the pandemic often proves to be too time-consuming and difficult.").

[86] *See generally id.* at 430–31 (regarding the COVID-19 pandemic, "[t]he Waiver proposal was submitted partly in response to the inequitable global distribution of COVID-19 vaccines, therapeutics, and diagnostics. Despite of the resistance by developed countries where big pharmaceutical companies are based, WTO members finally arrived at an agreement on the TRIPS Waiver proposal.").

[87] *Intellectual Property and Access to Health Technologies*, *supra* note 77.

[88] *Id.*

[89] *Id.*

[90] Aruna Kashyap & Margaret Wurth, *Waiving Intellectual Property Rules Key to Beating Covid-19*, HUMAN RIGHTS WATCH (Nov. 16, 2020, 2:00 AM), https://www.hrw.org/news/2020/11/16/waiving-intellectual-property-rules-key-beating-covid-19.

[91] *See* Richard Morgan, *HIV Prevention Drugs Illustrate Just How Bad Pharmaceutical Patents Are for Our Health*, NBC NEWS (Dec. 1, 2020, 4:31 PM), https://www.nbcnews.com/think/opinion/hiv-prevention-drugs-illustrate-just-how-bad-pharmaceutical-patents-are-ncna1249428 ("The problem with patents thus persists because toxic agents in soulless systems have created a ruthless market for its ostensible solutions.").

decision-making authority over how, where, and when to produce and distribute vaccines and treatments . . . ."[92]

B. CURRENT PUBLIC HEALTH AND ACCESS TO CARE ISSUES WITH PATENTS

With the ongoing need for public health treatment innovation, intellectual property plays a large role in the accessibility and creation of new life-saving pharmaceuticals. There are multiple areas of intellectual property created specifically to combat public health and pharmaceutical innovation and access barriers.

For example, The Federal Drug Administration created the Orange Book in 1979, a publication of approved drug products "identif[ying] drug products approved on the basis of safety and effectiveness . . . ."[93] The book combats high drug prices and patent abuse by mandating that pharmaceutical companies share patent information with regulatory agencies.[94] This patent sharing method, however, has failed to achieve its intended result of affordable and accessible medications.[95] On September 14, 2023, the FTC issued a policy statement warning pharmaceutical companies for improperly listing patents in the FDA's Orange Book catalog.[96] The issue of improper listings in the Orange Book creates "harm [to] competition from less expensive generic alternatives and keep[s] prices artificially high . . . ."[97]

Patents in isolation can also create a barrier to pharmaceutical access that greatly harms the public health of the nation.[98] This is because "patents give their holders monopoly rights for a certain period of time, during which the holders have nearly unrestricted power to set prices."[99] Investigation and comments highlight how high pharmaceutical company research and development ("R&D") costs and profit margins prevent access to needed

[92] Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, J. INT'L ECON. L. 1, 3 (2020).

[93] FDA, *Orange Book Preface*, *https*://www.fda.gov/drugs/development-approval-process-drugs/orange- book- preface#:~:text=The%20publication%2C%20Approved%20Drug%20Products,Act%20(the%20FD%26C%20Act) (last visited Feb. 11, 2024).

[94] Kelly Lienhard, *FTC Warns Drugmakers Against Listing Illegitimate Patents*, LAW360 (Sept. 14, 2023, 6:00 PM), https://www.law360.com/health/articles/1721446?nl_pk=38dc7049-0143- 4478- b68b- 07c60187555b&utm_source=newsletter&utm_medium=email&utm_campaign=health&utm_content=2023- 09- 15&read_main=1&nlsidx=0&nlaidx=7.

[95] FTC, *FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book'*, (Sept. 14, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug.

[96] *Id.*

[97] *Id.*

[98] Davey, *supra* note 38, at 690.

[99] *Id.* (citations omitted)

medications.[100] Branded manufacturers engage in patent abuse through "evergreening" which is creating "minor tweaks to small molecules by branded manufacturers to increase patent life" as well as "pay-for-delay" tactics which keep more cost effective generic medications away from consumers by keeping them off the market.[101] Isolated patents harm the public by incentivizing patent owners to withhold their findings from other organizations that could further public benefit.

Specifically, drug patents have created public health issues by creating drug scarcities. During the COVID-19 pandemic, numerous organizations sought to develop treatments for the viral disease including Gilead Sciences' drug, remdesivir.[102] Remdesivir began as an Ebola treatment and was then found to be effective against coronaviruses by shortening the recovery time for sick patients.[103] The Human Health Services secretary at the time declared COVID-19 a public health emergency which allowed the FDA to issue an Emergency Use Authorization for the medication.[104] This later resulted in shortages of remdesivir which "likely led to additional patient deaths."[105] The shortage was likely in large part caused by a denied compulsory license for remdesivir as other countries such as Bangladesh, Pakistan, and the Philippines, which had access to generics of the medication, did not have such shortages.[106]

Further, there is current litigation regarding technologies that have saved lives during the COVID-19 pandemic. Pfizer and BioNTech were sued by Promosome LLC in June 2023 because Promosome alleged that the companies' "COVID-19 vaccines infringe[d] a patent related to messenger ribonucleic acid technology that helps teach the body's immune system to recognize and attack disease-causing viruses."[107] The three parties were able to settle in October 2023.[108] Unfortunately, the patent on this lifesaving technology creates an access to treatment barrier during a public health emergency.[109]

With MRNA being a valuable piece of intellectual property, companies are utilizing these technologies and refusing to share this information with others through licensing strategies while gaining large profits during a public health state

[100] *Id.*
[101] *Id.* at 691.
[102] *Id.* at 700.
[103] Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 CONN. L. REV. 57, 82–83 (2022).
[104] *Id.* at 83.
[105] *Id.* at 85.
[106] *Id.* at 86.
[107] Craig Clough, *Biotech Co. Drops MRNA Patent Suit Against Pfizer, BioNTech*, LAW360 (Oct. 5, 2023, 9:32 PM), https://www.law360.com/articles/1729560?e_id=45fa9983-ab44-4c9e-a0d7-4c245bebb81c&utm_source=engagement-alerts&utm_medium=email&utm_campaign=case_updates.
[108] *Id.*
[109] *Id.*

of emergency.[110] Resources allocated to areas such as litigation and exclusivity could be utilized instead to further public benefit.

C. WHY PATENT POOLS ARE THE CORRECT INTELLECTUAL PROPERTY TOOL

1. Arguments Against Patent Pools Don't Hold Water

There are both benefits and drawback to patent pools. One of the most common arguments against patent pools is that they stifle competition and innovation.[111] Patent pools have also been criticized as being "expensive to negotiate, exclud[ing] patent holders with smaller numbers of patents or enabl[ing] a group of major players to form a cartel that excludes new competitors."[112] What is more, patent pools create unexpected costs because of their time to form and because they may require an outside expert to evaluate patents within the pool.[113] Although there are possible drawbacks, even the FTC has recognized the benefits and validity of patent pools.[114]

Further, when looking at the possible cons of patent pools, one needs to look beyond the influence on intellectual property law or the market in a vacuum. Patent pools that garner their greatest success should be viewed as a tool to aid public health, especially in times of emergency. The use of a mandatory patent pool would not create long-term negative effects, such as long-term use of an individual's invention, because it would be limited in scope and subject to the immediate needs at hand.

2. Benefits of Patent Pools

Patent pools have many benefits that can be translated into the public health and pharmaceutical sphere. Stated benefits of pools include their procompetitive nature through integration of complementary technologies, the reductions of transaction costs, clearing innovative roadblocks, and increasing the widespread sharing of technologies.[115] Patent pools show their efficiency and effectiveness when "multiple patented technologies are needed to produce a standardized product . . . . [These pools] are generally recognized as mitigating the 'holdup'

[110] *See id.* ("Moderna . . . learned the patented method from Promosome and then declined to license the technology despite using it in its own COVID-19 vaccine, according to the dismissed suit.").

[111] Cindy DeRuyter, *The Pros and Cons of Using a Patent Pool*, LEGAL ZOOM (Nov. 21, 2023), https://www.legalzoom.com/articles/the-pros-and-cons-of-using-a-patent-pool; *see also* Victor Rodriguez, *Patent Pools: Intellectual Property Rights and Competition,* NAT'L LIBR. MED. (Jan. 10, 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2831195/ ("Patent pools are subject to regulatory clearance because they could result in a monopoly.").

[112] Rodriguez, *supra* note 111.

[113] DeRuyter, *supra* note 111.

[114] *See* Anthony, *supra* note 2 (noting that patents pools can be procompetitive).

[115] Briggs, *supra* note 12, at 82.

and 'holdout' problems that can sometimes stymie industry efforts to make a product that conforms to an industry standard."[116]

Critics of patent pools note different concerns, mostly related to competition and antitrust laws. Such concerns include "distortion of competition caused by pooling competing patents."[117] While there is an inextricable tie to antitrust law and the possibility of antitrust violations with patent pools, there is unlikely to be an "anticompetitive effect[] unless (1) excluded firms cannot effectively compete in the relevant market for the good incorporating the licensed technologies and (2) the pool participants collectively possess market power."[118]

Although creating patent pools raises concerns of incentive and ownership over intellectual property innovations, patent pools allow for sharing of essential knowledge while still upholding intellectual property protections.[119] Patent pools can be created, and even made mandatory in times of public need, by the creation of "a system of compulsory patent pooling and licensing [that] . . . include[s] express suspension of any regulatory marketing exclusivity while ensuring that actual production remains dependent on demonstrating compliance with good manufacturing practice."[120]

3. Successful Public Health Patent Pools

Multiple patent pools within the public health sphere have been successful in the past and continue to be successful to this day. The Medicines Patent Pool ("MPP") was established in 2010 by Unitaid, a global health agency whose mission is to find innovative solutions and prevent, diagnose, and treat diseases more quickly and effectively.[121] The goal of the MPP is to create "non-exclusive voluntary licensing through a public health agency [to help] enable more people in [low- and middle-income countries] to access affordable treatments."[122] The MPP first worked in HIV treatment specifically and created an "established mechanism for licensing under public health-oriented terms and conditions that would enable manufacturers to develop quality-assured generic products."[123]

[116] *Id.*

[117] *Patent Pools and Antitrust – A Comparative Analysis*, *supra* note 13, at 10.

[118] Briggs, *supra* note 12, at 82.

[119] Abbott & Reichman, *supra* note 92, at 9 ("[A]llowing open access to . . . underlying technologies . . . . does not equate to eliminating patents.").

[120] *Id.* at 10.

[121] *See* Lauren Ulrich, *Trips and Compulsory Licensing: Increasing Participation in the Medicines Patent Pool in the Wake of an HIV/AIDS Treatment Timebomb*, 30 EMORY INT'L L. REV. 51, 51 (2015) ("The Medicines Patent Pool (MPP) is a collective action mechanism designed to overcome patent barriers resulting from the implementation of TRIPS in developing countries to respond to the treatment timebomb.").

[122] *About Us*, MEDS. PAT. POOL, https://medicinespatentpool.org/who-we-are/about-us (last visited Feb. 13, 2024).

[123] *Id.*

The MPP played a large role in the access of quick technology advancements in the treatment of COVID-19 during the pandemic's global health emergency.[124] The MPP created licensing agreements with the United States National Institutes of Health ("NIH") to develop innovative COVID-19 therapeutics, early-stage vaccines, and diagnostic tools.[125] These agreements were made to "allow greater access to these technologies and . . . lead to the development of commercial products that can address current and future public health needs."[126] The MPP has an "innovative business model" and partners with "civil societ[ies], governments, international ogani[z]ations, industr[ies], patient groups, and other stakeholders" in order to "pool intellectual property to encourage generic manufacture and . . . develop[] new formulations."[127]

The MPP's business model incorporates a multitude of layers and different organizations which allows it to function successfully. The business model starts with disease experts, civil society and patient groups, and partners who aid in addressing key public health issues.[128] Once treatment needs are identified, the MPP partners with WHO to prioritize needed pharmaceuticals.[129]

Next, the MPP gets patent holders to agree to license their medicine to the MPP.[130] The MPP then "sublicenses rights to manufacture these treatments to generic pharmaceutical companies."[131] Licensing through the MPP creates benefits that allow the pool to function, including: "[l]icensing terms [that] encourage the sale of low-cost versions of essential medicines and treatments," allowing more generic medicines in the market to bring down pharmaceutical prices and allowing greater access to medicines on a quicker timeline.[132]

The MPP has been able to track its successes to show that as of December 2022, the MPP has been able to save over $1.5 billion through its licenses and averted 27,000 deaths.[133] The MPP calculates its numbers by considering "the role of MPP licences in supporting expanded generic competition and the

[124] *See COVID 19*, MEDS. PAT. POOL, https://medicinespatentpool.org/covid-19 (last visited Apr. 12, 2024) ("During the COVID-19 pandemic, MPP's public health-oriented IP management model is providing that it can deliver, and that, if integrated earlier into future pandemic response, it could contribute to a more equitable response even more rapidly.").

[125] *WHO and MPP Announce Agreement with NIH for COVID-19 Health Technologies*, MEDS. PAT. POOL (May 12, 2022), https://medicinespatentpool.org/news-publications-post/who-and-mpp-announce-agreement-with-nih-for-covid-19-health-technologies.

[126] *Id.*

[127] *Id.*

[128] *Business Model*, MEDS. PAT. POOL, https://medicinespatentpool.org/who-we-are/business-model (last visited Feb. 13, 2024).

[129] *Id.*

[130] *Id.*

[131] *Id.*

[132] *Id.*

[133] *Impact*, MEDS. PAT. POOL, https://medicinespatentpool.org/progress-achievements/impact (last visited Jan. 1, 2024).

resulting effect on reducing drug prices."[134] According to the MPP's model, the "uptake of . . . products is influenced by prices, and that increased uptake of more affordable optimal products creates positive economic and health impact."[135] The MPP's benefit comes from both creating a large public health impact and by creating a high value with invested funds.[136] Part of MPP's goals for the years 2023 to 2025 include "[b]readth and scope of licenses" to provide aid to a greater population.[137]

The MPP has many safeguards in place to make sure that licenses are being implemented in an efficient and successful way.[138] The MPP "negotiates licenses with patent holders and licenses those patents to multiple manufacturers, who develop the licensed medicine, including new formulations and combinations."[139] MPP licenses have key features to aid in improved treatment options such as quality assured products through quality assurance policies, non-exclusive licenses to encourage generic competition, waivers for data exclusivity, transparency through publishing on MPP's website, and license management to ensure compliance and prevent "market leakage."[140] The MPP uses an Expression of Interest ("EOI") process for deciding who can license.[141] The EOI application is open to those wanting to license a patent license from the MPP.[142] Then, those that have applied find out if they are able to license within three to four weeks.[143] For the pool to be successful, the pool needs to continuously consider why organizations will benefit from joining the MPP.[144] Incentive to join may be one of the hardest parts of implementing a widespread voluntary patent pool and shows why creating a mandatory patent pool in times of emergency would be more effective than how the MPP currently operates.

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[134] *Id.*

[135] *Id.*

[136] *Id.*; *see also* Ulrich, *supra* note 121, at 60 ("Key to the MPP's success is that it negotiates licensing agreements from a global health rather than from a financial perspective and operates as an intermediary between patent holders and generic manufacturers.").

[137] *Our Strategy*, MEDS. PAT. POOL, https://medicinespatentpool.org/what-we-do/strategy (last visited Jan. 1, 2024).

[138] *How to Give or Get a License*, MEDS. PAT. POOL, https://medicinespatentpool.org/partners/how-to-get-or-give-a-licence#pills-How-to-get-a-licence-from-MPP (last visited Jan. 1, 2024).

[139] *Licensing for Public Health*, MEDS. PAT. POOL, https://medicinespatentpool.org/what-we-do/licensing-for-public-health (last visited Jan. 20, 2024).

[140] *The Medicines Patent Pool 2018-2022 Strategy*, MEDS. PAT. POOL, https://medicinespatentpool.org/uploads/2019/12/2018-2022_Strategy_EN.pdf (last visited Apr. 12, 2024).

[141] *How to Give or Get a License*, *supra* note 138.

[142] *Id.*

[143] *Id.*

[144] *Our Strategy*, *supra* note 137.

Although the MPP serves as a useful model of how a patent pool can be successfully implemented, the MPP uses voluntary licensing.[145] There can be issues with voluntary licensing that could harm public health during a health emergency. Some concerns involving voluntary licenses include "their territorial limitations, the extent to which some middle-income countries are often excluded, despite the significant and growing disease burdens in such countries."[146]

A second widespread public health patent pool, regarding the recent public health emergency for COVID-19, is C-TAP. C-TAP is a patent pool that provides "a single platform for the developers of COVID-19 health products—vaccines, tests, medical devices and treatments—to share their know-how, intellectual property (IP), and data with quality-assured manufacturers."[147] This legally allows manufacturers to access and sell COVID-19 treatments and therapeutics to provide greater access to a larger number of people during the pandemic.[148] C-TAP partnered with the MPP as well as the United Nations and Unitaid.[149] Through the MPP, C-TAP issues non-exclusive licenses that "aim to provide qualified manufacturers with: the legal rights to manufacture and sell the licensed products; the technology and know-how required to develop quality-assured products effectively and efficiently; [and] access to clinical data needed to obtain regulatory approval for their products."[150] C-TAP involves an "Open COVID Pledge" that asks pharmaceutical companies, treatment developers, and innovators to make their advancements in COVID-19 treatment available to other developers in order to fight against the virus.[151]

An empirical study was done by the National Library of Medicine on C-TAP.[152] The study found that based on the criteria of adaptability, scope of

[145] *Id.*

[146] *Intellectual Property and Access to Health Technologies*, *supra* note 77; *see id.* (noting that "by 2020 the majority of people living with HIV will likely reside in middle-income countries; and the majority of people living with hepatitis C currently live in middle-income countries.").

[147] *C-TAP – A Pioneering Approach to Enhance the Global Production of and Access to COVID-19 Health Products Through Transparent, Voluntary, Non-Exclusive Licensing*, WHO, https://www.who.int/initiatives/covid-19-technology-access-pool/what-is-c-tap (last visited Jan. 20, 2024); *see also* Luiza Pinheiro Alves da Silva & Marcia S. Rapini, *Suitability of Two WHO Research and Development Initiatives for COVID-19 to Promote Equitable Innovation: the Access to COVID-19 Tolls Accelerator and COVID-19 Technology Access Pool*, PAN AM. J. PUB. HEALTH 1, 3 ("C-TAP is a voluntary pool of intellectual property, clinical and regulatory data, know-how and other types of knowledge for the development and production of technologies for the detection, prevention, control, and treatment of COVID-19.").

[148] *C-TAP – A Pioneering Approach to Enhance the Global Production of and Access to COVID-19 Health Products Through Transparent, Voluntary, Non-Exclusive Licensing*, *supra* note 147.

[149] *Id.*

[150] *Id.*

[151] *Id.*

[152] da Silva & Rapini, *supra* note 147.

research, geographical scope, inclusive governance structure, experience in funding and research development, experience in managing research and development, and transparency, C-TAP scored relatively well receiving eleven out of a total of fourteen points.[153] The study further stated that "C-TAP is an initiative that proposes an innovative approach to intellectual property, aiming to reduce its impact as an access barrier."[154]

D. MANDATORY PATENT POOLS IN EMERGENCY SITUATIONS

The use of mandatory government intervention through patent pools in times of emergency and needed situations may seem overbearing but has taken place in other areas of the United States' government. For example, the government decides to take control over property and intellectual property rights to help the greater good through eminent domain, compulsory licensing, and more.[155] All of these examples show a time when the government found that "[t]he essential needs of the society as a whole may outweigh the . . . rights of an individual."[156] Other attempts of aid in public health emergencies have been seen through the Public Health Emergency Medicines Act in 2001, but the bill was only introduced to the House and never passed by congress.[157]

The recent COVID-19 pandemic highlighted the issues with the United States' current emergency public health response. The structure of intellectual property law creates mechanisms and systems that may function well in non-emergency situations with less of a risk and harm to public health.[158] However, the constraints of the system create issues for higher risk situations that cause great harm to a large population both within the United States and internationally.[159]

[153] *Id.* at 5.

[154] *Id.* at 6.

[155] Daniel R. Cahoy, *Treating the Legal Side Effects of CIPRO: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM. BUS. L. J. 125, 142–47 (2002).

[156] Lee*, supra* note 37, at 181.

[157] Public Heath Emergency Medicines Act, H.R. 3235, 107th Cong. (2001); *see also* Dawn Dziuba, *Trips Article 31bis and H1N1 Swine Flu: Any Emergency or Urgency Exception to Patent Protection?*, 20 IND. INT'L & COMP. L. REV. 195, 211 (2010) (discussing the standard compensation proposed by the bill).

[158] Karen Walsh, *Intellectual Property Rights and Access in Crisis*, NAT'L LIB. MED., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7940865/ ("The importance of access to intellectual property rights (IPR) protected subject-matter in . . . public health . . . has been extensively demonstrated during the COVID-19 pandemic. Although they involve separate legal areas, patent and copyright, the common threat linking the two is intellectual property's difficult relationship with access in the public interest.").

[159] Abbott & Reichman, *supra* note 92, at 3; *see also id.* ("[P]rivate sector controls will be grounded in intellectual property rights (IPRs), including patents and regulatory-based market exclusivity regimes.").

Without legal or governmental intervention, it is possible that private companies can create effective treatments to disease and not share this information with the public.[160] Private companies have the power to influence the entire population with no requirement to share their innovative technologies with others who are trying to further pharmaceuticals and treatment technologies that have a lifesaving effect.[161] Having a "[r]eliance on voluntary methods c[an] leave countries at the whim of the pharmaceutical industry, increasing both uncertainty and transaction costs."[162]

The idea of forcing the sharing of intellectual property may appear to threaten the current system, but it is already being done. In 1979, the World Intellectual Property Organization ("WIPO") granted compulsory patent licenses, and the WTO did the same.[163] Moreover, waivers are written into the current WTO agreement. Just as waivers can be created in times of need and for limited durations, mandatory patent pools can further be used as a tool to aid in public health emergencies.

Part of the issues of patent pools include lack of incentive to join because of the possible negatives of lost profit.[164] The MPP has been successful because of its ability to both focus from a public health standpoint and be "an intermediary between patent holders and generic manufacturers."[165] Similarly, the creation of a mandatory patent pool through government agencies such as the World Health Organization or Centers for Disease Control and Prevention can operate from a public health mindset.

The success of the MPP as an intermediary can be replicated in a government agency system to run and eliminate costs of people who run patent pools. Mandatory patent pools would also not take away intellectual property rights as licensing systems would still be set up to ensure proper compensation for intellectual property innovations. Mandatory patent pools could operate in a limited time frame structure where organizations would be placed into the pool during times of national emergency and the requirement of sharing innovative pharmaceuticals and treatment could end when national emergencies end.

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[160] *Id.*

[161] *See id.* ("[C]onstraints due to manufacturing capacity shortfalls are likely, particularly for vaccines. These constraints may be exacerbated if the technologies needed to address the pandemic are closely held by individual private enterprises . . . .").

[162] Davey, *supra* note 38, at 713.

[163] *See Paris Convention for the Protection of Industrial Property*, WORLD INTELL. PROP. ORG. (Sept. 28, 1979), https://www.wipo.int/edocs/lexdocs/treaties/en/paris/trt_paris_001en.pdf.

[164] *See* Ulrich, *supra* note 121, at 53 ("The MPP . . . faces its own problems in providing adequate incentives for patent holders to voluntarily license their HIV medicines patents to the pool.") (citations omitted).

[165] *Id.* at 60; *see also id.* ("The MPP's status as a non-financially-motivated intermediary is essential to its ability to negotiate licensing agreements that will increase access to more affordable patented medicines . . . .").

During World War I, the airplane industry attempted a mandatory patent pool.[166] The Wright airplane was patented on May 22, 1906.[167] The Wright's patent was litigated from 1909 to 1917 because it was broadly defined and "attempted to block nearly all airplanes as infringement upon their patent."[168] There was a truce in 1918 that involved the creation of a patent pool for airplane manufacturers.[169] The goal of this patent pool was to increase the manufacturing of airplanes in light of the war.[170]

This pool was implemented within the Manufacturers' Aircraft Association ("MAA").[171] The MAA was used as an "entity . . . to implement the cross-licensing agreement."[172] The United States government played a role through the National Advisory Committee for Aeronautics which proposed a cross-licensing agreement by creating an aircraft patent pool to "alleviate a patent hold-up among private aircraft manufacturers."[173]

The MAA's patent pool was later investigated by congress in 1935 due to antitrust concerns about the pool's monopolistic power.[174] The pool was found to reduce competition in the airplane innovation field.[175] The government further argued that such a cross-licensing agreement "hampered competition in research and development and that the amount of research and development in the aircraft industry would have been greater without the agreement."[176]

Although the patent pool was ultimately disbanded, "the . . . patent data . . . and half of the patent agreement likewise fail to support the idea that the purpose of the agreement was to suppress innovation."[177] Later analysis of the patent pool's influence on the industry showed that the MAA may not have had such a negative consequence on the airplane market and research and

[166] *See generally* Mfrs. Aircraft Ass'n v. United States, 17 U.S.P.Q. 439, 447 (Ct. Cl. 1933) ("[A]ll the patents on devices used on the airplanes were pooled and placed under the control of plaintiff and thereafter the Government . . . .").

[167] U.S. Patent No. 821,393 (filed Mar. 23, 1903).

[168] Anthony E. Chavez, *Exclusive Rights to Saving the Planet: The Patenting of Geoengineering Inventions*, 13 NW. J. TECH. & INTELL. PROP. 1, 28 (2015); *see also* Herbert A. Johnson, *The Wright Patent Wars and Early American Aviation*, 69 J. AIR L. & COM. 21, 21 (2004).

[169] Johnson, *supra* note 168, at 21.

[170] *Id.*

[171] *Id.* at 57; *see also* Chavez, *supra* note 168, at 28 ("Manufacturers of aircraft and related parts purchased a share of the association, enabling them to exercise licenses on key patents shared in the pool.") (citations omitted).

[172] Ron D. Katznelson & John Howells, *The Myth of the Early Aviation Patent Hold-Up – How a U.S. Government Monopsony Commandeered Pioneer Airplane Patents,* 24 INDUS. & CORP. CHANGE 1, 3 (2015).

[173] *Id.* at 1; *see also* George Bittlingmayer, *Property Rights, Progress, and the Aircraft Patent Agreement*, 31 J. L. & ECON., 227, 232 (1988).

[174] Johnson, *supra* note 168, at 58–59.

[175] Bittlingmayer, *supra* note 173, at 227–28.

[176] *Id.* at 235.

[177] *Id.* at 238.

development as the Court may have thought.[178] Just as a mandatory patent pool has been utilized in the past in times of dire need, a mandatory patent pool could be used in times of public health emergency. Although the MAA was at that time found to be anticompetitive, it was shown to have caused less harm on the airplane industry than previously suspected.[179]

IV. CONCLUSION

Overall, the current intellectual property law system regarding patents does not allow for the nation to operate with the needed haste and effectivity that is required during public health emergencies. Mandatory patent pools during public health emergencies could work in tandem with other intellectual property tools to aid in times where public health should trump intellectual property laws. Patent pools are appropriate tools that still provide just compensation to owners of intellectual property while facilitating space to share vital intellectual property and innovations. Temporary mandatory patent pools would set up a system to aid the public health of the nation while putting in safeguards for the owners of that technology. The benefits of patent pools outweigh the drawbacks, especially in times where the greater good and health of the nation is at stake.

Overall, the question is whether the value of public health is strong enough to trump individualistic values in current IP law and those that operate within it. The answer to this question is imperative to the success of implementing a mandatory patent pool.

[178] *Id.* at 240 ("[T]he agreement did not monopolize innovation in even the most narrowly defined subclasses recognized by the patent office . . . . [I]f the agreement succeeded in curtailing research and development expenditures, it did so in a limited area of technology, and it did not protect firms from rigors of competition.").

[179] *See id.* (noting that there was less harm than originally thought by the Court).